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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary

Application No.

09/674,768

Applicant(s)

NEUHAUS ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2-3 and 14-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, -13, and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1, 4-13, and 16 in Paper No. 19 is acknowledged. The traversal is on the ground(s) that Rule 13.2 was incorrectly applied, because the cited prior art does not teach the invention as a whole, and because the International search authority did not consider a lack of unity to be present. This is not found persuasive because the stated reference also teaches, in addition to plant transformation using the ADP/ATP translocator, that the ADP/ATP translocator plays a prominent role in the physiology of starch metabolism and that the activity of the ADP/ATP translocator can be limiting for the rate of starch metabolism and fatty acid biosynthesis.

Furthermore, the reference teaches the transformed plant cell as claimed, wherein the claimed phenotype appears to have been an inherent property. Regarding the failure of the International search authority to indicate a lack of unity, the Examiner notes that he is not bound by the decision of another Examiner. Contrary to Applicant's assertions, the instant lack of unity complies with PCT regulations.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 1 is objected to because of the following informalities: in line 1 "which is genetically modified" is redundant. Appropriate action is required.

Claim 11 is objected to because of the following informalities: Claim 11 should end in a period. Appropriate correction is required.

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Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). In the interests of compact prosecution, the claim will be treated on the merits. Such treatment does not relieve Applicant's of the responsibility to respond to this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a foreign nucleic acid molecule of unspecified length, source, and function.

Applicant describes PCR primers of SEQ ID NO: 1 and 2 for isolation of a cDNA encoding the AATP2 ADP/ATP translocator from *Arabidopsis*; AATP1-cDNA from *Arabidopsis* (Example 2, Kampfenkel *et al.*); and AATP1 from *S. tuberosum* (Example 3 Accession No. Y10821).

Applicant does not describe any other foreign nucleic acid molecules.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

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See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Given the failure of foreign nucleic acid molecules to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

Claims 1, 4-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the production of a transgenic potato plants transformed with the AATP1-cDNA gene from *Arabidopsis*, exhibiting an increased yield of starch and percent amylose content, does not reasonably provide enablement for a method for the production of a transgenic plant transformed with a foreign nucleic acid molecule of undefined source, length, and function, exhibiting an increased yield of starch and percent amylose content. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Applicant broadly claims a method for making a transgenic plant cell transformed with a foreign nucleic acid molecule that increases the plastidial ADP/ATP activity in the cell.

Applicant teaches a method for the production of a transgenic potato plants transformed with either the AATP1-cDNA gene from *Arabidopsis*, exhibiting an increased yield of starch and percent amylose content (Example 2 and 4); and transgenic potato expressing antisense AATP1-cDNA from potato, exhibiting a decrease yield of starch and percent amylose content (Example 3 and 4).

Applicant does not teach a method for the production of any transgenic plant transformed with a foreign nucleic acid molecule of undefined source, length, and function, exhibiting an increased yield of starch and percent amylose content.

The unpredictability in attempting to engineer increased and altered starch using a transgenic approach is illustrated in the example where constructs carrying an isoform of a starch branching enzyme cDNA in antisense orientation was introduced into potato, neither the amylose content of the starch in the tubers, nor the total starch content of the tubers was altered (Willmitzer *et al.*, Plant Polymeric Carbohydrates, 17/1993, pp. 33-39, page 38 lines 17-21).

Generally speaking, the possible and most likely presence of uncharacterized multiple isoforms of starch metabolic enzymes expressed in various tissue types of a plant through the developmental phases of growth as well as possible variation upon these patterns, especially during storage of starch, and given the polyploidic nature of many crop plants; transformation with a single isoform of a starch metabolic gene is a highly unpredictable factor to consider in any attempt to modify gene expression using a transgenic strategy (Anderson J. *et al.* In: The

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Molecular and Cell Biology of the Potato, Ch. 12, Vayda *et al.* eds., C.A.B. International: Wallingford, UK, 1990 on page 170, lines 4-17).

The isolation of orthologous DNA sequences from other species introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable either PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited homology. Thus the screen for orthologous sequences would isolate many genes other than those of interest. The inherent unpredictability in isolation of a homologous sequence encoding the same protein activity is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a range of enzymes involved in fatty acid metabolism (Broun *et al.* Science Vol. 282 13 November 1998; Abstract lines 4-6 and p. 1317 column 1, lines 51-56).

Given the lack of guidance, the absence of working examples in the specification that teach transformation using a foreign nucleic acid molecule of undefined source, length, and function for increasing starch production in any plant, the breadth of the claims, and the unpredictability in the art, undue trial and error experimentation would have been required by one skilled in the art to transform and regenerate a plant with sense or antisense constructs and evaluate a multitude of non-exemplified regenerated plants with increased starch production, and having increased amylose. Undue experimentation would have also been required to isolate a multitude of non-exemplified foreign nucleic acid molecules from a multitude of sources and to

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evaluate their ability to increase starch and amylose content in transformed plants. Therefore the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, line 2, "an introduction of" is indefinite because an introduction of the DNA does not indicate that the DNA is in any particular organelle or integrated into a genome; "a foreign nucleic acid molecule" is indefinite because it does not indicate whether the nucleic acid molecule is coding, non-coding, regulatory, or an individual nucleotide. The claim should read --transformation with a heterologous cDNA--.

At Claim 1, lines 2-3, "whose presence or expression leads to" is indefinite because it is suggested that expression of the DNA is not necessarily required for an increase in the translocator activity of the cell. The claim should read --wherein the expression results in the increase in plastidial ADP/ATP translocator activity--.

At Claim 10, line 3, "by means of introduction of" is indefinite because "by means of introduction of" the DNA does not indicate that the DNA is integrated into a genome.

At Claim 10, lines 3-4, "a foreign nucleic acid molecule" is indefinite because it does not indicate whether the nucleic acid molecule is coding, non-coding, or regulatory. The claim should read --transformation with a heterologous cDNA--.

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At Claim 10, line 4, "whose presence or expression leads to" is indefinite because it is suggested that expression of the DNA is not necessarily required for an increase in the translocator activity of the cell. The claim should read --wherein the expression results in the increase in plastidial ADP/ATP translocator activity--.

At Claims 5, 8, and 11, "and/or" is indefinite because it is unclear what is intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry *et al.* WO 96/24679.

Barry teaches increased levels of starch and production of a modified starch by an increased uniformity in potato transformed with a sucrose phosphorylase gene, *gtfA*, from *Streptococcus mutans* when compared to wild type on page 20-22; increased levels of starch in maize transformed with *atfA* when compared to wild type on pages 22-24. Since the reference teaches an increase in the biosynthesis of starch in both potato and maize and since the ADP/ATP translocator is rate limiting for starch biosynthesis the reference inherently teaches an increase in the plastidial ADP/ATP translocator activity in the transformed cells. Further, since the level of starch in the transformed plants is higher the level of amylose is inherently higher. Thus, the reference teaches all the limitations of Claims 1, 4-13, and 16.

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All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Russell Kallis Ph.D.
December 9, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title. The signature is stylized and cursive.